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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/994,937	ANDERSON, DAVID M.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-27,29-53,56,58-60 and 66-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-27, 29-53, 56, 58-60 and 66-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 26 2009 has been entered.

Receipt of Amendments/Remarks filed and Declaration under 37 CFR 1.132 on March 26 2009 is acknowledged. Claims 2, 28, 54-55, 57-58 and 61-65 were/stand cancelled. Claims 66-69 were added. Claims 1, 3-9, 14-19, 27, 29-34, 39-44, 52-53 and 56 were amended. Claims **1, 3-27, 29-53, 56, 58-60 and 66-69** are pending.

Upon further consideration, the examiner has decided to withdraw the species election. Therefore, all claims are examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Withdrawn Rejections

The rejection of claims 1, 3-19, 27, 29-44, 52-53, 56, 58-60 and 65 under 35 U.S.C. 103(a) as being unpatentable over Landh et al. (US Patent No. 5531925, cited in

the Office action mailed on 4/14/08) in view of Benet et al. (US Patent No. 5716928, cited in the Office action mailed on April 6 2006) and Yau et al. (US Patent No. 5541287, cited in the Office action mailed on 4/14/08) as evidenced by The Merck Index (2006, cited in the Office action mailed on 4/14/08) is **withdrawn** in light of Applicant's arguments and the Declaration filed on March 26 2009.

Response to Arguments and Rule 132 Declaration

The declaration under 37 CFR 1.132 filed March 26 2009 is sufficient to overcome the rejection of claims 1, 3-19, 27, 29-44, 52-53, 56, 58-60 and 65.

Applicant's arguments, see page 16 through page 17 bridging paragraph, filed March 26 2009, with respect to the rejection(s) of claim(s) 1, 3-19, 27, 29-44, 52-53, 56, 58-60 and 65 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is deemed necessary. The following represents all new grounds of rejection.

The following represents all new grounds of rejections presented in this Office action.

Claim Objections

Claim 9 is objected to because of the following informalities: the claim recites "claim I" as opposed to claim 1. The Roman numeral should be replaced with the

number 1 (or what ever claim number the claim is desired to depend from). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-14, 52 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as ascorbyl palmitate and stearylamine or riboflavin derivatives of water-soluble vitamins, which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim(s) **1, 3-14, 52 and 60** is(are) directed to encompass **amphiphilic derivatives**, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these derivatives meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The

specification provides insufficient written description to support the genus encompassed by the claim. **Note: MPEP 2163.**

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed **derivatives** regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Circ. 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, (Fed. Cir. 1991). In Fiddes v. Baird, 30 USPQ2d 1481, 1483, (Bd. Pat. App. & Int. 1993), claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention,

> with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 22-26 and 47-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 as currently written is vague and indefinite. The claim recites "said lipid or surfactant is a surfactant that is a pharmaceutical active is difficulty soluble in water". It is unclear what exactly applicants are attempting to claim. Is the surfactant attempting to be limited to a pharmaceutical active that is difficult to solubilize in water or is applicant attempting to claim a surfactant and a pharmaceutical active that is difficult to solubilize in water or something else? The language of the claim is indefinite.

Claims 22-26 and 47-51 as currently written are vague and indefinite. The claims recite the dissolution/solubilization "agent comprises". The term agent would indicate a singular chemical entity. Therefore, the claims as written are vague and indefinite because it is unclear how a chemical entity can comprise a chemical. Other pending claims recite "agent is" which would be the more appropriate language when referring to a chemical entity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-15, 17-19, 21-24, 27, 29-40, 42-44, 46-49, 52-53, 56, 59-60 and 66-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (WO 9912640).

Applicant Claims

The instant application claims a composition comprising A) a reversed cubic liquid phase or a reversed hexagonal liquid crystalline phase or a combination thereof comprising a polar solvent, a surfactant or lipid, and an essential oil or a dissolution/solublization agent or both; and B) a compound that is solubilized in the structured fluid.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Anderson is directed to coated particles that comprise an internal core comprising a matrix and an exterior coating. The matrix consists essentially of at least one nanostructure liquid phase or at least one nanostructured liquid crystalline phase or a combination of the two. Exemplified compositions comprise Paclitaxel, eugenol, soy lecithin, glycerol and cupric nitrate or paclitaxel, anisole and water (examples 36 and 37). The nanostructured liquid crystalline phase material include reversed cubic phase, reversed hexagonal phase, reversed intermediate phase and lamellar phase (page 33 lines 9-13). The nanostructured liquid crystalline phase material may be formed form a polar solvent, a surfactant and an amphiphile or hydrophobe (page 34, lines 7-11). Surfactants include phospholipids (page 35, lines 4-14) and block polymers of

polyethylene oxide and polypropylene oxide such as poloxamer 188 (page 36, lines 22-24). The amphiphile and hydrophobe component includes natural oil extracts such as anise oil, clove oil, peppermint oil; terpenes; eugenol; vitamin E, etc. (pages 37-38 lines 29-32 and 1-4). Polar solvents include water, glycerol, etc. (page 38, lines 5-13). Examples of active agents when can be solubilized include estrogens such as hexestrol (page 46, line 19). Coating materials include gentisic acid which are utilized to provide protection against oxidation, hydrolysis, degradation, etc. (page 42, line 1). It is taught that the examples can be utilized in delivery of Paclitaxel for cancer treatment (example 36). It is taught that since the components of the formulation are on the FDA list of approved inactive excipients for oral delivery (and nearly all of them for injection as well) that the formulation can be very important as a drug-delivery formulation for the treatment of cancers (example 38).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

While not expressly stating that the exemplified compositions are reversed hexagonal or reversed cubic phases comprising paclitaxel, a polar solvent, a lipid or surfactant, and eugenol, Anderson does teach that the compositions of the invention can comprise a inner matrix which is a crystalline phase material which includes reversed cubic and reversed hexagonal phases.

While Anderson does teach that the hydrophobe and amphiphile components includes essential oils such as peppermint oil; and vitamin E, Anderson does not exemplify these components in combination with paclitaxel.

While Anderson teaches suitable surfactants include poloxamers, Anderson does not exemplify these surfactants in combination with paclitaxel.

While Anderson does teach that since the components of the formulation are on the FDA list of approved inactive excipients for oral delivery (and nearly all of them for injection as well) that the formulation can be very important as a drug-delivery formulation for the treatment of cancers, Anderson does not exemplify orally administering (internally administering) the drug delivery formulation.

While Anderson teaches that gentisic acid can be incorporated, Anderson does not exemplify utilizing gentisic acid.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention formulate a composition wherein the paclitaxel is dissolved in a polar solvent, lipid or surfactant and eugenol wherein the phase comprising these components is a reversed cubic or reversed hexagonal liquid crystalline phase. One of ordinary skill in the art would have been motivated to utilize a reversed cubic or reversed hexagonal liquid crystalline phase as Anderson teaches that the inner matrix can be a crystalline phase in which reversed cubic or reversed hexagonal phases are two of the four choices for these particular phases. It would have been obvious to one of ordinary skill in the art to try any of the specifically taught phase fluids as a person with ordinary skill has good reason to pursue known options within his or her technical grasp. **Note: MPEP 2141 [R-6]** *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize essential oils such as peppermint oil or Vitamin E (tocopherol) in the drug delivery formulation. One of ordinary skill in the art would have been motivated to utilize peppermint oil or Vitamin E as both are taught by Anderson as preferred components for the hydrophobe and amphiphile components. One of ordinary skill in the art would have been motivated to replace eugenol with peppermint oil or Vitamin E as all are taught by Anderson as functional equivalents.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize poloxamers in the drug delivery formulation of Anderson. One of ordinary skill in the art would have been motivated to utilize poloxamers as these surfactants are one ingredient required by the compositions and these are surfactants that are exemplified by Anderson.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to orally administer the drug delivery formulations of Anderson. One of ordinary skill in the art would have been motivated to orally administer the drug formulations as Anderson teaches that the components of the formulation are on the FDA list of approved inactive excipients for oral delivery that the formulation can be very important as a drug-delivery formulation for the treatment of cancers. Therefore, this teaching by Anderson suggests to one of ordinary skill in the art to administer the drug delivery formulations comprising paclitaxel orally for the treatment of cancers.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize gentisic acid in the drug delivery formulation. One of ordinary

skill in the art would have been motivated to utilize gentisic acid as it is specifically taught as a component that can be incorporated into the formulations in order to provide protection against oxidation, hydrolysis, degradation, etc. Therefore, one of ordinary skill in the art would have been motivated to add this component for it's protective nature as taught by Anderson.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 16 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Unger et al. (US Patent No. 6090800).

Applicant Claims

The instant application claims specific essential oils such as 1,8-cineole.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Anderson are set forth above. Specifically, Anderson teaches drug delivery formulations comprising paclitaxel, polar solvents, lipid or surfactants and an amphiphile and hydrophobe component. This component includes terpenes as well as essential oils. Other drugs are indicated as suitable for incorporation into the drug delivery formulation.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Anderson does teach the incorporation of 1,8-cineole. However, this deficiency is cured by Unger et al.

Unger et al. teach solubilizing agents for use with a delivery vehicle include terpenoids such as 1,8-cineole as well as essential oils such as eucalyptus (columns 79-80, lines 57-67 and 1-34).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Anderson and Unger et al. and utilize solubilizing agent such as 1,8-cineole. One of ordinary skill in the art would have been motivated to utilize 1,8-cineole as Anderson teach that the amphiphile and hydrophobe component includes terpenes. This provides the motivation to one of ordinary skill in the art to look to specific terpenes for incorporation. Therefore, one of ordinary skill in the art would have been motivated to utilize 1,8-cineole as they are specific terpenoids which are known to be utilized for drug solubilization.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 20 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Wehling et al. (US Patent No. 5223264).

Applicant Claims

The instant application claims specific essential oils such as bay oil.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Anderson are set forth above. Specifically, Anderson teaches drug delivery formulations comprising paclitaxel, polar solvents, lipid or surfactants and an amphiphile and hydrophobe component. This component includes terpenes as well as essential oils. Other drugs are indicated as suitable for incorporation into the drug delivery formulation.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Anderson does not specify that a essential oil that can be incorporated is bay oil. However, this deficiency is cured by Wehling et al.

Wehling et al. teach that known essential oils include eucalyptus, anise, bay oil, peppermint oil, clove oil, etc. (column 7, lines 5-15).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Anderson and Wehling et al. and utilize other known essential oils such as bay oil. One of ordinary skill in the art would have been motivated to utilize other essential oils such as bay oil as Anderson teach that the amphiphile and hydrophobe component includes essential oils. This provides one of ordinary skill in the art to look for specific essential oils. Wehling et al. teach that known essential oils include those such as peppermint and anise, which are taught by

Anderson, as well as clove oil. Therefore, since Anderson teach the incorporation of essential oils one of ordinary skill in the art would have been motivated to add bay oil as it is a specific type of essential oil.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 25-26 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Yamakawa et al. (JP 08143475).

Applicant Claims

The instant application claims that the dissolution/solubilization agent is tryptophan.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Anderson are set forth above. Specifically, Anderson teaches drug delivery formulations comprising paclitaxel, polar solvents, lipid or surfactants and an amphiphile and hydrophobe component. This component includes terpenes as well as essential oils. Other drugs are indicated as suitable for incorporation into the drug delivery formulation.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Anderson does not teach incorporating the amino acid tryptophan. However, this deficiency is cured by Yamakawa et al.

Yamakawa et al. (utilizing the machine generated English Translation) is directed to methods for dissolving slightly soluble medicine utilizing tryptophan (paragraph 0001). Tryptophan is blended with a slightly soluble medicine and the solubility of a slightly soluble medicine is improved remarkably (paragraph 0006).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Anderson and Yamakawa et al. and utilize tryptophan in the drug delivery formulation. One of ordinary skill in the art would have been motivated to add tryptophan in order to increase the solubility of poorly soluble drugs based on the teachings of Yamakawa et al. Therefore, when desiring to delivery drugs with are poorly soluble it would have been obvious to one of ordinary skill in the art to incorporate tryptophan in order to increase drug solubility.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 3-16, 18, 27, 29-41, 43, 52-53, 56, 59, 66 and 68-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engstrom et al. (US Patent No. 5151272) in view of Unger et al.

Applicant Claims

The instant application claims a composition comprising A) a reversed cubic liquid phase or a reversed hexagonal liquid crystalline phase or a combination thereof comprising a polar solvent, a surfactant or lipid, and a essential oil or a dissolution/solubilization agent or both; and B) a compound that is solubilized in the structured fluid.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Engstrom et al. claim a composition for controlled release of selected bioactive material in vivo; the composition comprising a cubic liquid crystalline phase or a reversed hexagonal liquid crystalline phase formed from monoglyceride material, lipid and water. The hydrophilic domain includes glycerol and the lipid bilayer includes phospholipids (claims 1-11). Drugs for delivery include antibiotics, proteins, steroids, vitamins and nucleic acids (claim 6).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Engstrom et al. do not specify the incorporation of 1,8-cineole or essential oils. However, this deficiency is cured by Unger et al.

Unger et al. teach solubilizing agents for use with a delivery vehicle include terpenoids such as 1,8-cineole as well as essential oils such as eucalyptus and yang ylang (columns 79-80, lines 57-67 and 1-34).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Engstrom et al. and Unger et al. and utilize essential oils such as eucalyptus and yang ylang as well as terpenoids such as 1,8-cineole in the composition. One of ordinary skill in the art would have been motivated to incorporate essential oils or terpenoids as Unger et al. teach that these components are known for solubilizing steroids. Therefore, since Engstrom et al. teach that one drug to be delivered include steroids, it would have been obvious to one of ordinary skill in the art to incorporate essential oils and terpenoids in order to aid in their solubilization based on the teachings of Unger et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 17, 25-26, 42 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engstrom et al. in view of Yamakawa et al.

Applicant Claims

The instant application claims that the dissolution/solubilization agent is tryptophan.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Engstrom et al. are set forth above. Specifically, Engstrom et al. teach composition for drug delivery comprising a cubic liquid crystalline phase or a reversed hexagonal liquid crystalline phase formed from monoglyceride material, lipid and water. The hydrophilic domain includes glycerol and the lipid bilayer includes phospholipids.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Engstrom et al. does not teach incorporating the amino acid tryptophan. However, this deficiency is cured by Yamakawa et al.

Yamakawa et al. (utilizing the machine generated English Translation) is directed to methods for dissolving slightly soluble medicine utilizing tryptophan (paragraph 0001). Tryptophan is blended with a slightly soluble medicine and the solubility of a slightly soluble medicine is improved remarkably (paragraph 0006).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Engstrom et al. and Yamakawa et al. and utilize tryptophan in the drug delivery formulation. One of ordinary skill in the art would have been motivated to add tryptophan in order to increase the solubility of poorly

soluble drugs based on the teachings of Yamakawa et al. Therefore, when desiring to delivery drugs with are poorly soluble it would have been obvious to one of ordinary skill in the art to incorporate tryptophan in order to increase drug solubility.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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